K000270

MAR - 7 2000

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576 3723

Contact person: Priscilla A Hamill

Date prepared: January 26, 2000

Predicate device

The ELECSYS® Cortisol Test System is equivalent to other devices legally marketed in the United States. We claim equivalence to the Enzymun® Cortisol test (K900485).

Device Name

Proprietary name: ELECSYS® Cortisol Test System

Common name: Cortisol Test

Classification name: Radioimmunoassay, Cortisol

Device description

The ELECSYS® Cortisol Test System a two step competitive immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code.

510(k) Summary, continued

Intended use

For the quantitative determination of Cortisol in human serum and plasma.

Indication for use

The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

Substantial equivalence - similarities

The following table compares the ELECSYS® Cortisol Test System, with the predicate device.

Feature	New Device ELECSYS® Cortisol Test System	Predicate Device (Enzymun Test® Cortisol)
Intended use	For the quantitative determination of Cortisol	For the quantitative determination of Cortisol
Indication for use	For recognition and treatment of functional disorders of the adrenal gland.	For diagnosis of the function of the adrenal gland, the pituitary, and the hypothalamus
Sample type	Human serum and plasma	Human serum and plasma

Substantial equivalence - differences

The following table compares the ELECSYS® Cortisol Test System, with the predicate device.

Feature	New Device ELECSYS® Cortisol Test System	Predicate Device (Enzymun Test® Cortisol)
Assay principle	Electrochemiluminescence immunoassay employing the competition principle.	Competition for capture of serum and conjugated POD-cortisol on antibody-coated tube. Detection of bound cortisol conjugate by measurement of POD activity.
Instrument	Roche ELECSYS® 2010 and 1010 Immunassay analyzers	Boehringer Mannheim automated immunoassay systems
Measuring range	0.036-63 µg/dL	1.0-47 µg/dL
Expected values	Mornings 8-25 µg/dL Afternoon 8-20 µg/dL Evening <6 µg/dL	2-25 µg/dL Mornings 7-25 µg/dL Evenings 2-9 µg/dL

Substantial equivalence – performance characteristics

The performance characteristics of the ELECSYS® Cortisol Test System and the predicate device are compared in the table below.

Feature	New Device ELECSYS® Cortisol Test System	Predicate Device (Enzymun Test® Cortisol)
Assay principle	Electrochemiluminescence immunoassay employing the competition principle.	Competition for capture of serum and conjugated POD-cortisol on antibody-coated tube. Detection of bound cortisol conjugate by measurement of POD activity.
Instrument	Roche ELECSYS® 2010 and 1010 Immunassay analyzers	Boehringer Mannheim automated immunoassay systems
Measuring range	0.036-63 µg/dL	1.0-47 µg/dL
Expected values	Mornings 8-25 µg/dL Afternoon 8-20 µg/dL Evening <6 µg/dL	2-25 µg/dL Mornings 7-25 µg/dL Evenings 2-9 µg/dL

Substantial equivalence – performance characteristics, continued

The performance characteristics of the ELECSYS® Cortisol Test System and the predicate device are compared in the table below.

Feature	New Device ELECSYS® Cortisol Test System	Predicate Device (Enzymun Test® Cortisol)
Within-Run precision (%CV) on Elecsys® 2010	1.3% at 7.53 µg/dL 1.3% at 20.3µg/dL 1.1% at 46.0 µg/dL 1.4% at 13.2 µg/dL 1.0% at 31.4 µg/dL	5.5%CV at 2.7 µg/dL 2.6%CV at 26.9 µg/dL 5.5% CV at 38.0 µg/dL
Within-Run precision (%CV) on Elecsys® 1010	3.2% at 7.31 µg/dL 3.1% at 13.7 µg/dL 2.2% at 19.8 µg/dL 2.6% at 14.0µg/dL 2.1% at 33.4 µg/dL	
Total precision (%CV) on Elecsys® 2010	1.6% at 7.53 µg/dL 1.5% at 20.3µg/dL 1.6% at 46.0 µg/dL 1.6% at 13.2 µg/dL 1.4% at 31.4 µg/dL	7.2%CV at 2.7 µg/dL 2.2%CV at 28.0 µg/dL 7.9% CV at 38.2 µg/dL
Total precision (%CV) on Elecsys® 1010	4.2% at 7.31 µg/dL 5.0% at 13.7 µg/dL 3.8% at 19.8 µg/dL 5.6% at 14.0µg/dL 5.4% at 33.4 µg/dL	
Analytical sensitivity	0.036 µg/dL	1 µg/dL
Functional sensitivity	0.29 µg/dL	Not specified
Method comparison	Elecsys® Cortisol (Y) comparison to predicate device (X): Slope = 1.11 Y-intercept = -25.3	Comparison Enzymun Cortisol (Y) to Baxter Cortisol Fluorometric (X) Immunoassay Assays Slope = 1.29 Y-intercept = 2.05

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2000

Ms. Priscilla Hamill
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K000270
Trade Name: ELECSYS® Cortisol Test System
Regulatory Class: II
Product Code: CGR, JIS
Regulatory Class: I
Product Code: JJY
Dated: January 26, 2000
Received: January 28, 2000

Dear Ms. Hamill:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A

Device Name: **ELECSYS® Cortisol Test System**

Indications For Use: **For the in vitro quantitative determination of cortisol in human serum and plasma.**

The determination of cortisol is used for the recognition and treatment of funtional disorders of the adrenal gland.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000270

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)